Good morning. My name is Andrew Pavia and I am representing the Infectious Diseases Society of America. IDSA represents almost 10,000 infectious disease physicians and scientists with wide-ranging expertise in clinical medicine, microbiology, basic science, biodefense and public health.

We appreciate the opportunity to comment on the potential development of an FDA-licensed MedKit containing doxycycline for home stockpiling in the event of an anthrax attack.

We appreciate the need to have an effective system to complete dispensing of effective countermeasures within 48 hours of the detection of an anthrax attack. To this end, we support the concept of forward positioning in areas where the risk is high to decrease the time to dispensing. We also support the need for effective countermeasure dispensing to emergency service workers who will have to respond to an attack.

The most effective dispensing systems will be those that are adapted to local situation, not a one-size fits all approach. Effective systems will use many strategies, taking into account the local capacities and risk. This likely will involve a variety of forward positioning strategies including work place dispensing and closed PODS and must include effective use of vaccines.

Sound principles should guide the choice of countermeasure dispensing measures. These include balancing the incremental benefits with the risks, ensuring equity of access, and sound stewardship of biodefense and other public health resources.

The issue at stake is whether the incremental benefits of home stockpiling compared to other effective forward positioning outweigh the incremental risks of placing antibiotics in a very large number of households most of whom will never need them for anthrax.

The calculus can be thought of as “Additional benefit times the probability it will ever be needed balanced against risks and costs specific to home stockpiling.”

Thus while home stockpiling may fill certain specific needs we have grave concerns about its use as a broad strategy.
Home stockpiling of antibiotics, including the use of an FDA-approved MedKit poses a number of challenges.

- The incremental benefit of home stockpiling relative to workplace caches, postal distribution systems and other effective dispensing is unclear.
- The risks of placing a large amount of antibiotic in homes are clearly significant. However, we cannot quantify them with available data. These include:
  - To what degree will people access and take antibiotics appropriately when instructed and will they refrain from taking them for other illnesses?
  - Can doxycycline in MedKits be effectively used to treat children?
  - The risks of inappropriate use when it occurs include:
    - Adverse events, ranging from rashes to life threatening conditions such as *Clostridium difficile* disease
    - Further selection of resistance. Significantly, this may include to drugs other than tetracyclines because of the presence of TCN resistance genes on multidrug resistance plasmids allowing doxycycline use to select for multidrug resistance
- Replacing outdated drug and safe disposal are critical issues that must be addressed. Flushing antibiotics into the sewer system is likely to further drive drug resistance
- The IOM report raised significant doubts about the cost effectiveness of large scale home stockpiling strategies relative to other methods.

As noted in the IOM report, the research conducted to date is wholly inadequate to answer a number of critical questions. We suggest the following research and development priorities.

- Develop and evaluate a variety of methods of rapid work-site based dispensing for first responders and their families
- Assess the costs and effectiveness of different forward positioning strategies
- Develop plans for replacement and safe disposal and evaluate costs
- Conduct detailed evaluations of the feasibility of home stockpiling in a variety of populations including
  - Ability to store and find the countermeasures
  - Ability to understand and follow instructions for use
  - Ability to prepare pediatric dosing
  - Probability and risk factors for inappropriate use
- Develop adequate planning for drug-resistant anthrax scenarios.